

L.P.H. (195/48) Department.

ms SERIES.

Letter
G.O. No. 1026

Dated 30-3-48

[Despatch Abstract.]

DESPATCH : Miscellaneous draft amendments to the Drugs Rules, 1945 - views of the Government Communicated to the Government of India.

No.F.1-53/47-D.
Government of India.
Ministry of Health.

New Delhi, the 20th November, 1947.

From

S. Devanath, Esquire, B.A.(Hons).,
Assistant Secretary to the Government of India.

To

All Provincial Governments.

Subject:- Miscellaneous draft amendments
to the Drugs Rules 1945.

....

I am directed to forward a copy of a draft notification containing various amendments to the Drugs Rules 1945. Some of these have already been considered by the Drugs Technical Advisory Board and others are calculated to make the intention quite clear or to remove obvious grammatical errors or misprints. A statement showing the need for the proposed amendments is enclosed. I am to enquire whether the Provincial Government agree to the Drugs Technical Advisory Board being consulted for the purpose of making the amendments on these lines in the provincial Drugs Rules. If the Provincial Government agree, the Central Government will consult the Drugs Technical Advisory Board on behalf of itself and the Provincial Government and communicate the views of the Drugs Technical Advisory Board. Further action for the amendment of the Central and the Provincial Rules can be taken after the views of the Drugs Technical Advisory Board are obtained. The favour of a very early reply is requested.

I have the honour to be,

Sir,

Your most obedient servant,

(Sd) S. Devanath
19.11.1947.

Assistant Secretary.

Education & Public Health Department

Endorsement No. 92617-G1/47-1 Public Health d/27.11.47.

Referred to the Surgeon-General for very early remarks.

(Sd) S. Devanath.

Assistant Secretary.

To
The Surgeon-General
with the Government of Madras.

/True Copy/

SP/23.6.

DRAFT NOTIFICATION.

The following draft of certain further amendments to the Drugs Rules, 1945, which it is proposed to make in exercise of the powers conferred by sections 12 and 33 of the Drugs Act, 1940 (XXIII of 1940), is published as required by the said sections for the information of all persons likely to be affected thereby and notice is hereby given that the draft will be taken into consideration on or after the Any objections or suggestions which may be received from any person in respect of the said draft before the date specified will be considered by the Central Government.

A. DRAFT AMENDMENTS.

1. In rule 2 - (1) for clause (f) the following clause shall be substituted, namely:--

"(f) 'Sale by way of wholesale dealing' means sale to a person for the purpose of selling again and includes sale to a hospital, dispensary, medical or research institution and to a registered medical practitioner for supply to his own patients.";

(2) Clause (g) shall be renumbered as clause (h); and (3) before the clause as so re-numbered the following clause shall be inserted, namely:--

"(g) 'Retail Sale' means a sale other than a sale by way of wholesale dealing".

II. In rule 37(1) Sub-rule (1) shall be renumbered as rule 37; and sub-rule (2) shall be omitted.

III. To rule 74, the following clause shall be added, namely:--

"(e) The licensee shall either (i) provide and maintain to the satisfaction of the licensing authority adequate staff and adequate laboratory facilities for carrying out such tests of the strength, quality and Purity of the substances manufactured by him as may be required under the provisions of these rules or (ii) make arrangements with some institution approved of by the licensing authority for such tests to be carried out regularly on his behalf by that institution

IV? In rule 100 -

(1) In clause (a) of the proviso to sub-rule (2) after the words "British Pharmaceutical Codex" the words "or in any other prescribed Pharmacopoeia" shall be inserted;
(2) for sub-rule (3) the following shall be substituted, namely:-- "(3) In the case of a preparation included in the British Pharmacopoeia or the British Pharmaceutical Codex, or in any other prescribed pharmacopoeia, or any dilution or admixture of such preparation or any surgical dressing for which a standard is prescribed in the British pharmaceutical Codex, it shall be sufficient, notwithstanding anything contained in the foregoing sub-rules to state the name, synonym or abbreviated name used to describe the preparation or surgical

dressing in the British Pharmacopoeia or the British Pharmaceutical Codex, or in any other prescribed pharmacopoeia, with the addition of the letters, "B.P.", or "B.P.C." or such letters as may be recognised abbreviations for other prescribed pharmacopoeias as the case may be".

.. For sub-rule (5) of rule 101, the following sub-rule shall be substituted, namely:-

"(5) In the case of a preparation included in the British pharmacopoeia or the British pharmaceutical Codex or in any other prescribed pharmacopoeia or any dilution or admixture of such a preparation or a surgical dressing for which a standard is prescribed in the British Pharmaceutical Codex the container of which is labelled with the name used to describe the article in the British Pharmacopoeia or the British pharmaceutical Codex or in any other Prescribed pharmacopoeia with the addition of letters "B.P.", abbreviations for other prescribed pharmacopoeias, it shall not be necessary to state on the label the quantity of alcohol or the preparation of the substance specified in Schedule E contained in the preparation."

VI. In rule 102, the words and figures "and tested for sterility by the process prescribed by Rules under the Drugs Act, 1940" shall be omitted.

VII. For rule 104, the following rule shall be substituted, namely:-

"104. Use of letters B.P., B.P.C., etc. The letters B.P., B.P.C. and other recognised abbreviations shall be entered on the label on a drug only for the purpose of indicating that the drug is in accordance with the standard set out in the British Pharmacopoeia, the British Pharmaceutical Codex or any other Prescribed pharmacopoeia as the case may be".

VIII. In rule 106, for the words "of women" the words "in women" shall be substituted.

B. In the Schedules annexed to the said Rules.

I. In Schedule A.(1) in Form 3, for paragraph 4 the following paragraph shall be substituted, namely:-

"4. A fee of rupees fifty has been credited to Government under the head of account "XXVII - Medical - Miscellaneous - Fees under the Drugs Rules, 1945 - Central" - vide treasury receipt attached."

(2) In Form 6 after paragraph 1 the following paragraph shall be inserted, namely:-

"2. A fee of rupees fifty has been credited to Government under the head of account "XXVII - Medical - Miscellaneous - Fees under the Drugs Rules, 1945 - Central" - vide treasury receipt attached."

(3) To the paragraph in Form 8 the following paragraph shall be added, namely:--

"A fee of rupees ten has been credited to Government under the head of account "XXVII - Medical - Miscellaneous - Fees under the Drugs Rules, 1945 - Central" - Vide treasury receipt attached."

(4) In Form 14-A, after item 6 the following item shall be inserted, namely:--

"7. A fee of rupees Vide Schedule B to the Drugs Rules, 1945, has been credited to Government under the head of account "XXVII. Medical - Miscellaneous - Fees under the Drugs Rules, 1945 - Central" - Vide treasury receipt attached."

(5) In form 15, for the words "Provisions or" the words "Provisions of" shall be substituted.

(6) In Form 19, after item 4 the following item shall be inserted, namely:--

"5. A fee of rupees five/ten has been credited to Government under the head of account "XXVII. Medical - Miscellaneous - Fees under the Drugs Rules, 1945 - Central" - vide treasury receipt attached."

(7) In Form 20, the mark" " against paragraph 3 shall be omitted.

(8) For Form 21 the following shall be substituted, namely:--

"FORM 21
(See rule 61(2))

License to sell, stock and exhibit for sale and distribute, biological and other special products specified in Schedule C.

..... is hereby licensed to sell, stock and exhibit for sale and distribute on the premises situated at the following drugs being drugs specified in Schedule C to the Drugs Rules, 1945.

Names of drugs.

2. This license will be in force for two years from the date given below

3. Name(s) - qualified person (s) in charge .

4. The licence is subject to the conditions stated below and to the provisions of the Drugs Act 1940 and the rules thereunder.

Date Licensing Authority.

Conditions of Licence

1. This licence shall be displayed in a prominent place in a part of the premises open to the Public.

2. The licensee shall report forthwith to the licensing authority any change in the qualified staff in charge.

3. No drug to which this licence applies shall be sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it has been in the possession of the licensee

11. If the licence is required for wholesale dealings only delete and enter the word 'wholesale'."

(9) In Form 24, after item 3 the following ite shall be inserted, namely:--

"4. A fee of rupees twenty has been credited to Government under the head of account "XXVII - Medical - Miscellaneous - Fees under the Drugs Rules, 1945 - Central Vide treasury receipt attached."

(10) In Form 27, after paragraph 3 the following paragraph shall be inserted, namely:--

"4. A fee of rupees twenty and an inspection fee of rupees.

An inspection fee of rupees one hundred have been credited to Government under the head of thirty has account "XXVII - Medical - Miscellaneous - Fees under the Drugs Rues, 1945, 1945 - Central" - Vide treasury receipt attached.

II. In Schedule E -

(1) To the entry "Creosote from wood" the following be added, namely:-

"except substances containing less than 50% of creosote".

(2) To the entry relating to Phenols, the following shall be added, namely:-

"except medicines with less than 1% of Phenol nasal sprays mouthwashes, pastilles, lozenges, capsules, pessaries, ointments or suppositories containing less than 2.5% of phenol".

(3) An asterisk shall be inserted against each of the following entries and the foot-note" * This item is also subject to the provisions of the Dangerous Drugs Act, 1930" shall be added.

Acetyldihydrocodeinone	Dihydromorphine.
Benzoyl morphine	Dihydromorphinone.
Benzylmorphine	Ecgonine
Coca	Ethylmorphine
Cocaine	Morphine
Dodeine	Thebaine
Diamorphine	Cannabis
Dihydrocodeinone	Opium
Dihydrozycodeinone	Pethidine Hydrochloride.

III. In Schedule F -

(1) In Part 1, under the heading "(B) - Provisions applicable to the production of Vaccine Lymph (Veccinis Vaccine)". for sub-clauses (3) of clause 4 the following shall be substituted, namely:-

"(3) (a) Immediately before the Vaccinal material is collected, the animal should be killed. Subsequently, a thorough post-mortem examination of the carcass shall be made by a qualified expert. A complete record of each such examination shall be kept and shall be open to inspection by or on behalf of the licensing authority at any time. If the examination reveals any conditions which indicate or suggest that the animal was suffering from any communicable disease (other than vaccinia) the lymph obtained from that animal shall not be issued; or

(b) when it is decided that post-mortem examination is not to be carried out, the animal shall not be killed, but shall be kept under observation for a period of at least forty-eight hours after collection of lymph. If during this period the examination reveals any conditions which indicate or suggest that the animal is suffering from any infection other than vaccinia the lymph obtained from that animal shall not be issued."

(2) In part IV, under the heading "(L) Provisions applicable to Antivenom Serum (Antivenens)" (a) for clause 2 the following clause shall be substituted, namely:--

"2. Standard preparations: No recognised standard venoms are at present available."

(b) For clause (a) of sub-clause (1) of clause 5, the following shall be substituted, namely:--

"(a) the potency of one cubic centimetre of the original antiserum from which the product has been prepared. This will be expressed as the neutralising value of the serum, under the method of test employed, against venoms of each species of poisonous snake from which it has been prepared."

IV.

In Schedule J -

(1) after the entry "Infantile Paralysis" the entry "Insanity" shall be inserted; and

(2) the entry "Lunacy" shall be omitted.

/True Copy/

EDUCATION & PUBLIC HEALTH DEPARTMENT

Letter 1026, Public Health dated 30-3-1946.

Ms.

To

The Secretary to the Government of India,
Ministry of Health, New Delhi.

Sir,

Miscellaneous draft amendments to the Drugs
Rules, 1945.

With reference to the Government of India's letter No. F.153/47-D dated 20th November, 1947 on the subject mentioned above, I am directed to state that this Government agree to the Drugs Technical Advisory Board being consulted, on behalf of this Government, for the purpose of making amendments, on the lines indicated in the draft notification appended to the letter, to the Provincial Drugs Rules, subject to the following modifications:-

(1) The amendment to Form 14-A should provide for crediting the fees to the provincial government for test or analysis by ~~the~~ Provincial Government analyst, Hence, after the proposed item 7 in Form 14-A the following item may be inserted in the Madras Drugs Rules, namely:-

"8. A fee of rupees Vide Schedule B to the Drugs Rules, 1945, has been credited to Government under the head of account "XXVII - Medical - J. Miscellaneous - Receipts under the Drugs Act, 1940."

(2) As regards item (5) of the amendments under B-I, there is no such misprint in the Madras Drugs Rules.

(3) As regards the proposed amendments to Forms 19 and 24, amendments similar to those proposed will be incorporated in the Madras Drugs Rules. Hence, after item 4 in Form 19 the following item may be inserted in the Madras Drugs Rules namely:-

"5. A fee of rupees five/ten has been credited to Government under the head of account "XXVII - Medical - J. Miscellaneous - Receipts under the Drugs Act, 1940"; and after item 3 in Form 24 the following item may be inserted in the Madras Drugs Rules namely:-

"4. A fee of rupees twenty has been credited to Government under the head of account "XXVII - Medical - J. Miscellaneous - Receipts under the Drugs Act, 1940".

(4) Rule 75 of the Madras Drugs Rules Provides for a fee of Rs. 20/- and an inspection fee of Rs.100/- for an application for the grant or renewal of licences to manufacture drugs specified in Schedule C and C(1). Rule 82 provides for an inspection fee of Rs. 30/- for grant of a licence after a further inspection, in case of rejected applications for licence in the first instance. Since these inspections will be done by the Board of Inspection and the panel of Inspectors, whose activities are guided and co-ordinated by the Central Government, it is presumed that the inspection fees of Rs.100/- and Rs. 30/- should be credited to the central Government and that the Provincial Government is entitled only

to the licence fee of Rs. 20/- of the position is as stated above necessary amendments may be made to provide for the credits of fees to the central and Provincial Governments respectively.

2. I am also to request that the views of the Drugs Technical Advisory Board may be communicated to this Government in due course.

(Sd)
15.3.48.

To
Copy to Surgeon-General.

/True Copy/

SP/24.6.

Superintendent
Madras Record Office.
2/7

No.F.1-53/47-D.
Government of India.
Ministry of Health.

New Delhi, the 1st April, 1948.

From

J.N. Saksena, Esquire, E.A.;
Assistant Secretary to the Government of India.

To

The Secretary to the Government of Madras,
Education and Public Health Department,
Madras.

Sir,

I am directed to refer to this Ministry's letter No. F. 1-53/47-D, dated the 20th November, 1947 regarding miscellaneous amendments to the Drugs Rules, 1945 which inter alia contains an amendment to Rule 101 (5) of the Central Drugs Rules, 1945 and to say that this amendment when incorporated in the rules, would clarify that preparations included in the B.P. or any other standard prescribed by the Drugs Rules need not indicate the alcohol content so long as the necessary addition "B.P." or "B.P.C." etc., is made to the name of the item on the label. It might however take a considerable time before the amendments are made to the Rules. Therefore, in order to enable the firms to make arrangements for printing labels it is suggested that pending final publication of the amendment in question, the firms may be allowed to print their labels without indicating the alcohol strength of the preparations included to the Standard recognised by the Drugs Act and Rules.

I have the honour to be,

Sir,

Your most obedient servant,

J.N. Saksena

Assistant Secretary.

EDUCATION & PUBLIC HEALTH DEPARTMENT
(GI)

Endorsement: 25048-G1/48-1 Public Health dated 9-4-1948.

Communicated to the Surgeon-General for
information and necessary action.

(Sd)
9.4.48.

To
The Surgeon-General with
a copy of Government of India's
letter above.

/True Copy/

SP/24.6.

No.F.1-53/47-D.
Government of India.
Ministry of Health.

New Delhi, the 3rd April, 1948.

From

J.N. Saksena, Esquire, B.A.,
Assistant Secretary to the Government of India.

To

The Secretary to the Government of the United
Provinces,
Public Health Department,
LUCKNOW.

Subject: Miscellaneous draft amendments to the
Drugs Rules. 1945.

Sir,

With reference to your letter No. 5518/XVI-4130/47 dated the 7th February, 1948, I am directed to say that the draft amendments circulated with this Ministry's letter No. F.1-53/47-D, dated the 20th November, 1947, related to the Central Drugs Rules. Wherever necessary, suitable modifications will have to be made to suit the Provincial Rules. So far as the forms referred to are concerned, similar amendments will no doubt be necessary to the corresponding forms under the provincial Rules. I am to request that copies of draft amendments to the forms worded so as to suit the Provincial Drugs Rules may also be kindly supplied to this Ministry for placing them before the Drugs Technical Advisory Board.

I have the honour to be,

Sir,

Your most obedient Servant,

(Sd) J.N.Saksena.
Assistant Secretary.

No.F.1-53/47-D.

Copy with a copy of the letter under reply forwarded to the Secretary to the Government of Madras, Education & Public Health Department, Madras.

By Order,

J.N. Saksena
Assistant Secretary.

/True Copy/

SP/24.6.

Copy of letter No. 5518/XVI-413(3) 47, dated the 7th February, 1948, from the Deputy Secretary to the Government of U.P., Public Health Department Lucknow, to the Ministry of Health.

Subject:- Miscellaneous draft amendments to the Drugs Rules, 1945.

.....

With reference to the Government of India, Ministry of Health letter No.F.1-53/47-D, dated November 20th 1947, I am directed to say that this Government agree to the Drugs Technical Advisory Board being consulted with regard to the proposed amendments except those relating to forms numbers 14A 19,24 and 27 of the Drugs Rules, 1945. The addition of a paragraph to these forms indicating the Central head to which the licence fees received is to be credited will lead to the impression that all licence fees received from the U.P. Drugs Rules will also be credited to the Central Revenues. This Government, therefore, consider that a reference to this head should be left blank and it should be filled in according to the requirement of each province.

/True Copy/

SUPERINTENDENT

SP/24.6.

Madras Record Office.

EDUCATION & PUBLIC HEALTH DEPARTMENT
(GI)

From the Government of India No. F.1-50/47-D
dated 30-11-1948.

...

Miscellaneous draft amendments to the Drugs Rules, 1945.

.....

The Government of India in their letter No. F. L 53/47-D dated 20-11-1947 have suggested certain amendments to the Central Drugs Rules. On a reference from the Government of Uttar Pradesh on this subject, the Government of India have informed them that the Provincial Drugs Rules will have to be amended on the lines of the Central Drugs Rules and that draft amendments to the Provincial Drugs Rules should also be forwarded to them for placing before the Drugs Technical Advisory Board.

2. This Government have already taken action on these lines in letter/Ms.No. 1026, Public Health dated 30-3-1948. No action is therefore necessary by the Government. The papers may be stitched with Letter No. 1026, Public Health dated 30-3-1948.

(Sd)
14.5.48.

/True Copy/

SP/24.6.

SUPERINTENDENT
Madras Record Office.